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| **Site Information** |

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| **Name of Legal Entity:** |  |
| Address: |  |
| Phone: |  |
| Fax: |  |

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| --- | --- |
| **Type of Practice**: | University/Hospital  Community/Private Practice |
| **IRB Information**: The Jaeb Center for Health Research (JCHR) IRB is accredited by AAHRPP and able to enter into an IRB Reliance Agreement to serve as the IRB for institutions participating as clinical sites. **Do you anticipate that your site will allow the use of JCHR accredited central IRB?** | Yes  No  Uncertain |
| **FWA Number (US Sites):** |  |
| **Estimated time to obtain IRB approval and execute a contract agreement:** | \_\_\_\_\_\_\_ months |
| **Does your site have a database from which to identify potentially eligible patients?** | Yes  No |
| **Percent of patients expected to be able to enroll in My Retina Tracker:** | 0%-25%  25%-50%  50-75%  75-100% |

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| **General Office Requirements Met:**   * Internet access in exam rooms (wireless or wired) * Separate email addresses for each staff member * Secure (limited access) location for study files | Yes  No  Uncertain |

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| **Site Information** |

**Approximate number of patients with IRDs in this practice**

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| --- | --- | --- | --- |
| **IRD** | **# patients total** | **# seen in last 5 years** | **# with confirmed genotyping (of those seen in last 5 years)** |
| LCA/SECORD |  |  |  |
| Dominant RP |  |  |  |
| XLRP |  |  |  |
| Simplex or ARRP |  |  |  |
| Stargardt |  |  |  |
| Cone-Rod Dystrophy |  |  |  |
| Usher Syndrome I |  |  |  |
| Usher Syndrome II |  |  |  |
| Usher Syndrome III |  |  |  |
| Bardet-Biedl |  |  |  |
| Achromatopsia |  |  |  |
| XLRS |  |  |  |

**Equipment**

**Please note** the following equipment is required for Consortium studies (indicate whether you have plans to obtain this equipment): **Octopus 900 Pro and Heidelberg Spectralis.**

The following equipment is preferred for Consortium studies (indicate whether you have plans to obtain this equipment): **MAIA; E-ETDRS Visual Acuity (EVA) Tester; and Diagnosys Espion.**

|  |  |  |
| --- | --- | --- |
| **Equipment** | **Manufacturer** | **Model** |
| ETDRS VA system |  |  |
| SD-OCT |  |  |
| Color Photography |  |  |
| Widefield Imaging |  |  |
| Fundus Autofluorescence |  |  |
| Full Field ERG |  |  |
| Multifocal ERG |  |  |
| Static perimeter |  |  |
| Kinetic perimeter |  |  |
| Fundus-guided perimetery |  |  |
| Dark Adaptometry/FST |  |  |
| Pupillometry |  |  |
| Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |

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| **Personnel Information** |

1. **Investigators**

***Please list the investigator intended to be the Principal Investigator first.***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Name** | **Degree** | **Email** | **Experience in sponsored clinical trials? (Yes/No) If yes, include clinical trial experience on CV** |
| **PI** |  |  |  |  |
| Co-I |  |  |  |  |
| Co-I |  |  |  |  |

**Attach all investigators’ current, signed1 and dated CV that details training and previous sponsored clinical study experience (including role as PI, co-Inv, as well as NCT number and # pts enrolled in each trial).**

**1Note: Signature on CV must be either a traditional handwritten signature or a 21 CFR Part 11 compliant digital signature from a certified program or where authentication of the signatory can be verified, such as Nitro or DocuSign.**

1. **Requirements for Investigator Qualifications**

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| **Investigators must meet at least ONE of the following. Please check those that apply. Add additional columns as necessary.** | | | |
|  | PI (Name) | Co-I  (Name) | Co-I  (Name) |
| (1) completion of a 1 year retina advanced specialty training program |  |  |  |
| (2) completion of a 1-2 year retina clinical fellowship program |  |  |  |
| (3) recognized expert in the field of IRDs based on previous clinical research publications and experience as a PI |  |  |  |

1. **Study Coordinators**

***Please list the coordinator intended to be the Primary Coordinator first.***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Name** | **Email** | **Years experience in clinical setting** | **Years experience in clinical trials** |
| **Primary** |  |  |  |  |
| Additional |  |  |  |  |
| Additional |  |  |  |  |

1. **Genetic Counselors**

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| --- | --- |
| **Name** | **Please indicate whether on site or otherwise accessible (provide detail)** |
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1. **Technicians**

***Please list names and ‘X’ in boxes for equipment for which individual has experience. If Years Experience varies by type of equipment, please list for each (e.g. VA=5, Photo=10) under that column***

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | **VA** | **OCT** | **Photo** | **ERG** | **Perimetrist** | **FA** | **Years Experience** |
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**Key:**

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| --- | --- |
| VA: VA Technician | ERG: ERG Technician (full field or multifocal) |
| OCT: SD-OCT Technician | Peri: Perimetrist (static, kinetic, or fundus-guided) |
| Photo: Photographer (color or widefield) | FA: Fundus Autofluorescence Technician |

1. **Access to Source Data**

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| As noted in the Governance Document, any study data for which direct data entry into the e-CRF is not the source will need to be accessible to the CC. |
| 1. Will access to the source documents be permitted? |
|  |
| 1. Does your institution require any additional steps (beyond language in contract and informed consent form) to allow CC to access medical records or other source when applicable? |
|  |
| 1. Does your site use electronic medical records (EMR)? If so, how will protocol monitors be given access to EMRs? |
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| 1. Will you be able to obtain medical records from patients who are not usually seen by the site? |
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1. **Citations from Regulatory Bodies or Agencies**

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|  | **Response** |
| How many FDA or regulatory audits has the site been involved in? |  |
| How many 483’s (FDA) or comparable audit observations has the site received? |  |
| Have any investigators listed ever been debarred or received a warning letter from the FDA or other regulatory agencies, or are currently under investigator for such actions? *If yes, please provide appropriate supporting documentation.* |  |
| Have any other study staff lost licensing or credentials, or is currently under investigation of such an action? *If yes, please provide appropriate supporting documentation.* |  |

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| **Study Suggestions (Optional)** |

1. **Patient Population**

**Please describe a patient population that FFB Consortium should study, and provide a rationale**

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1. **Key Design Elements**

**Please describe the proposed sample size, duration, and key outcome measures**

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1. **Expected number of patients your site would be able to enroll with suggested IRD:**

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1. **Alternative Studies**

**Please describe alternative patient populations that you think are worthwhile studying**

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